

Application No. 10/771,803
Amendment dated
Reply to Office Action of June 14, 2007

Docket No.: 023189.0101PTUS

AMENDMENTS TO THE DRAWINGS

The attached sheet(s) of drawings add Figures 8A and 8B.

Attachment: New sheet

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REMARKS

In view of the above amendments and the following remarks, applicant believes the pending application is in condition for allowance.

Upon entry of this Amendment, claims 1-34 are pending, of which, claims 1, 7, 19, 23 and 29 are independent. No new matter has been added by this amendment. Support for the claim amendments/new claims can be found at, for example, publication paragraphs 11, 21, 24, 26, 28, 30-36, and 38 and Figs. 1, 4, 6, and 7.

Personal Interview

Applicant's representative, Michele Frank, and Mr. Tony Wondka thank Examiner Mitchell for the courtesies extended during the personal interview on Friday November 2, 2007. A summary of the interview is incorporated into the following remarks. We look forward to allowance of the claims. As discussed, if any additional questions arise, we welcome Examiner Mitchell to contact the undersigned, Michele Frank.

Supplement Information Disclosure Statements

It is respectfully requested that the Examiner consider, initial, sign and return the appropriate part of the Information Disclosure Statement filed October 30, 2007 and the Information Disclosure Statement filed herewith.

Priority

The Examiner noted that Applicant has not yet filed a certified copy of the German priority application. Applicant has requested a certified copy of the priority document and will forward it to the Office as soon as it is received.

Drawings

The drawings have been objected to as failing to comply with 37 C.F.R. 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: sensor 3. Tracheal prosthesis is designated 2, 3 and sensors are designated 8, 9, for example, all of which are shown in

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the drawings, for example, Figs. 3-4. Applicant is not aware of a sensor "3". Applicant believes that all is in order. Clarification or withdrawal of the objection is respectfully requested.

The drawings have been objected to under 37 C.F.R. 1.83(a), for failing to include the double-lumen design for the catheter. As discussed and shown during the interview, Applicant adds and attaches new Figures 8A and 8B to show this embodiment. No new matter has been added. Withdrawal of the objection is requested.

Abstract

The Abstract of the Disclosure has been objected to because the Abstract is longer than 159 words.

Applicant submits herewith a new Abstract of the Disclosure. Withdrawal of the objection is requested.

Specification

The disclosure has been objected to because of the following informality: on page 6, line 2, "... 150 mm..." should be "— 50 ml --.

Applicant has corrected the specification as indicated. Withdrawal of the objection is respectfully requested.

Oath/Declaration

The Examiner has stated that the declaration is defective, and that a new one is required, identifying this application by application number and filing date, and the acknowledgement of the duty of disclosure. A substitute declaration executed by the inventor is attached.

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Rejections under 35 U.S.C. § 103

Claims 1-7, 13 and 17 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Bennarsten (6,694,978). This rejection is respectfully traversed.

Claim 1 calls for a method for supporting the respiration of a patient. The steps include identifying the inspiratory and expiratory breathing using at least one "spontaneous respiration sensor adapted to sense the breathing of the patient." An additional amount of oxygen gas is administered "cyclically in synchrony" with the patient's "spontaneous breathing pattern" via a "transtracheal catheter" placed into the airway "without occluding the airway to create an open ventilation system."

Bennarsten is directed to a High Frequency Oscillation (HFO) ventilator where a patient may feel suffocated if the patient has an inspiratory effort. Therefore, a conventional ventilator is included in parallel with the HFO ventilator so if the patient produces an inspiratory effort the conventional ventilator is activated to deliver a full mechanical assisted breath to the patient so that the patient does not fight the HFO ventilator.

Bennarsten is directed to a "closed" system where the patient either breathes from the HFO ventilator or the conventional ventilator; the patient is not expected to breathe ambient air, rather the "closed" conventional ventilation system is always breathing for the patient. (See, e.g., col 4, lines 31-34.) In contrast, claim 1 calls for identifying the inspiratory and expiratory breathing using at least one "spontaneous respiration sensor adapted to sense the breathing of the patient" and an "additional amount" of oxygen gas can be administered "cyclically in synchrony" with the patient's spontaneous breathing pattern via a "transtracheal catheter" placed into the airway "without occluding the airway to create an open ventilation system." In accordance with the invention of claim 1 the patient can maintain spontaneous breathing allowing the patient to continue to exercise their breathing muscles and maintain/improve their lung mechanics. By sensing the patient's spontaneous breathing, oxygen gas can be administered to the patient; the patient is breathing from ambient and the oxygen gas supplements the patient's natural breathing. This is accomplished through the claimed transtracheal catheter placed in the airway "without occluding the airway creating an open ventilation system," among other features of the claimed invention.

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Additionally, the Bennarsten monitoring device detects "a spontaneous breathing effort" during HFO ventilation so the conventional ventilator can kick in and to provide the full mechanical assisted breath so the patient does not fight the HFO ventilation. (See, e.g., Bennarsten col. 1, lines 10-12.) Bennarstens' sensors trigger switching on the mechanical ventilator from an "off" condition to an "on" condition based on the patient "effort" to breathe. It does not disclose or suggest identifying inspiratory and expiratory breathing and/or a spontaneous respiration sensor adapted to sense the breathing pattern of the patient. Bennarsten merely detects an "effort."

Withdrawal of the rejection of claim 1 and its dependent claims for the additional features recited therein is respectfully requested.

Independent claim 7 calls for an apparatus for supporting the respiration of a patient. A catheter connected at one end to an oxygen pump and the other end inserted transtracheally into the trachea so as to "not occlude the airway to create an open ventilation system." The at least one "patient respiration" sensor is for detecting the spontaneous respiration phases of the patient.

Bennarsten fails to disclose or suggest the features of claim 7 at least for the reasons discussed above. Claim 7 and its dependent claims for the additional features recited therein define patentable subject matter. Withdrawal of the rejection is respectfully requested.

Claims 8-12 and 14-16 are rejected under 25 U.S.C. § 103(a) as being unpatentable over Bennarsten (6,694,978) in view of Hebeler, Jr. (5,054,484) and Whitwam et al. (4,644,947). This rejection is respectfully traversed.

At least for the reasons discussed above with respect to the independent claims, dependent claims 8-12 and 14-16 further define patentable subject matter for the features recited therein. Withdrawal of the rejection is respectfully requested.

Claims 19-22 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Hebeler, Jr. (5,054,484) in view of Whitwam et al. (4,644,947) and Bennarsten (6,694,978). This rejection is respectfully traversed.

Independent claim 19 calls for a tracheal prosthesis with a connection for a jet catheter and at least one sensor couples with the support body of the tracheal prosthesis. The prosthesis is configured to not occlude the tracheal airway to create an open ventilation system so that the patient

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is "always breathing spontaneously past the prosthesis" and the sensor is in the spontaneous breathing airflow in the trachea and is "not" in line with the gas flow from the ventilator.

Hebeler discloses a transtracheal T-piece stent that is convertible to a tracheostomy tube by inflating a gland inside the proximal section of the stent so that it can be switched either from spontaneous breathing through the upper airway to mechanical ventilation by connection of the mechanical ventilator to the outside portion of the T. When used for mechanical ventilation the gland 20 is inflated in the upper section of the T-tube and the ventilator is attached to the outer end 16a of T-tube. With Hebeler, the system can be a closed system for 100% breathing by a ventilator or a system for 100% breathing by the patient.

Whitwam discloses a respirator with a jet (11) applied to the respirator tubing (5) outside the patient to drive the gas into the tubing and into the patient. The jet is applied to the tubing outside the patient to drive the column of gas in the tubing into the patient. The system is a closed system. (See, e.g., Figs. 1, 2, 4.)

Bennarsten was discussed above.

The ventilator systems disclosed in Hebeler, Whitwam and Bennarsten are "closed" type ventilation systems (as described above). Accordingly, the patient does not breathe spontaneously and have additional oxygen administered without occluding the airway and in synchrony with the patient's spontaneous breathing pattern. The patient cannot talk, drink, eat, swallow and/or cough. By contrast, claim 19 calls for, among other things, an apparatus that does not occlude the airway to create "an open ventilation system" so that the patient is "always" breathing spontaneously past the prosthesis. Independent claim 19 further calls for a tracheal prosthesis with a connection for a jet catheter and at least one sensor coupled with the support body of the tracheal prosthesis. The prosthesis is configured to not occlude the tracheal airway to create an open ventilation system so that the patient is "always breathing spontaneously past the prosthesis" and the sensor is in the spontaneous breathing airflow in the trachea and is "not" in line with the gas flow from the ventilator. With the claimed invention the open transtracheal catheter system is suited for wearable and mobile use of the system. As an "open" system it allows the patient to breath, speak and eat normally while in use.

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Alone or in combination, Hebel, Whitwam and Bennarsten fail to disclose or suggest the invention as set forth in claim 19 and its dependent claims 20-22.

Claims 23-26 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Whitwam et al. (4,644,947) in view of Bennarsten (6,694,978). This rejection is respectfully traversed.

Independent claim 23 has been amended to call for a catheter for delivering ventilation to a patient. One end of the catheter is attached to a ventilator and the opposite end is inserted transtracheally into a trachea of a patient to no occlude the tracheal airway to create an open ventilation system. The respiratory sensor is on the inserted end of the catheter and is "not" in line with the gas flow lumen of the catheter and "is" in line with the spontaneous breathing airflow of the trachea.

Whitwam discloses a respirator with a jet (11) applied to the respirator tubing (5) outside the patient to drive the gas into the tubing and into the patient. The jet is applied to the tubing outside the patient to drive the column of gas in the tubing into the patient. The system is a closed system. (See, e.g., Figs. 1, 2, 4.) The system is for critical care.

Whitwam fails to disclose the claimed transtracheal catheter that does not occlude the tracheal airway to create an open ventilation system and/or the respiratory sensor on the inserted end of the catheter and therefore, further fails to disclose that the sensor is "not" in line with the gas flow lumen of the catheter and "is" in line with the spontaneous breathing airflow of the trachea.

The Office Action takes the position that Whitwam discloses a catheter and Bennarsten teaches sensors to detect changes in spontaneous breathing effort and that it "would have been obvious to one of ordinary skill in the art to place at least two sensors affixable to the catheter of Whitwam because placing the sensors on the body would provide a means to receive output signal for low pressure to detect changes induced by spontaneous breathing effort as taught by Bennarsten." (Office Action at pages 9-10.)

There is no motivation to combine Whitwam and Bennarsten. Whitwam is jetting a column of gas into the patient and there would have been no motivation to provide Whitwam with the Bennarsten ventilation pressure sensor other than to meet the claim language. But, even if

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combined, the combination of Whitwam and Bennarsten fail to disclose, at least, the claim 23 transtracheal catheter that does not occlude the tracheal airway to create an open ventilation system as claimed. As discussed above, both Whitwam and Bennarsten are closed type systems (described in more detail above). Nor, does the combination disclose or suggest the claimed spontaneous breath sensors for sensing spontaneous breathing in the trachea and not in line with the gas flow from the ventilator.

Added independent claim 29 calls for a method of providing respiratory support to a spontaneously breathing patient with a catheter ventilation system. The step of delivering supplemental volume to a patient via a transtracheal catheter, wherein the supplemental volume delivery into a trachea is in the form of a jet from a catheter tip, and wherein the catheter does not obstruct the airway and is an open ventilation system, and the supplemental volume delivery is cyclical and synchronized with the patient's inspiratory and/or expiratory spontaneous breath phase. The step of detecting the patient's spontaneous breathing by an intra-tracheal respiration sensor which measures intra-tracheal airflow. And, the step of providing mobility to the patient by the catheter ventilation system being wearable by the patient.

Alone or in combination, Hebeler, Whitwam and Bennarsten fail to disclose or suggest the invention as set forth in claim 29.

U.S. Patent No. 5,279,288 to Christopher was previously cited and signed-off by the Examiner in a prior Information Disclosure Statement submitted by Applicant. This patent was discussed during the Examiner interview. As discussed, Christopher discloses a system for augmenting ventilation and removing carbon dioxide of a spontaneous breathing patient by providing high "continuous" flow of a humidified oxygen/air mixture at a predetermined oxygen content and at a constant flow rate. Transducers and alarms are used to monitor oxygen content, flow rate, pressure, temperature and humidity. (See, e.g., Christopher at col. 8, lines 26-29.) Although an "open" system, Christopher does not disclose or suggest "breath" sensors for detecting the spontaneous breathing and/or synchronous administration of the oxygen gas.

Pursuant to this paper, Applicants submit that pending claims 1-26 and new claims 27-34 are in condition for further examination and allowance, which action is hereby requested.

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No fees other than those cited hereinabove should be due in connection with the filing of this paper. However, if any additional fees are found to be required, the Office is hereby authorized to charge any and all such fees to Deposit Account No. 50-2228.

Dated: November 14, 2007

Respectfully submitted,

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Attachment:
New Drawing Sheet